

# PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

**PCT**

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

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in its capacity as elected Office

Date of mailing (day/month/year)

22 February 1999 (22.02.99)

International application No.

PCT/US98/13093

Applicant's or agent's file reference

5722-2P-1

International filing date (day/month/year)

24 June 1998 (24.06.98)

Priority date (day/month/year)

25 June 1997 (25.06.97)

Applicant

BLACK, Charles, Allen, Jr.

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

08 January 1999 (08.01.99)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was



was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Jean-Marie McAdams

Telephone No.: (41-22) 338.83.38

## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

09/446402

REC'D 12 APR 1999

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Applicant's or agent's file reference 5722-2-1	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US98/13093	International filing date (day/month/year) 24 JUNE 1998	Priority date (day/month/year) 25 JUNE 1997
International Patent Classification (IPC) or national classification and IPC IPC(6): C07H 21/02; C12N 5/10, 15/87 and US Cl.: 435/69.1, 375; 536/24.5, 25.2		
Applicant BLACK, CHARLES ALLEN, JR.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

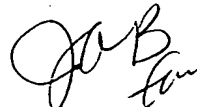
2. This REPORT consists of a total of 3 sheets.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  08 JANUARY 1999	Date of completion of this report  25 MARCH 1999
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231  Facsimile No. (703) 305-3230	Authorized officer  THOMAS G. LARSON, PH.D.   Telephone No. (703) 308-0196

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/13093

**I. Basis of the report**

1. This report has been drawn on the basis of *(Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments):*

☒ the international application as originally filed.

☒ the description, pages 1-29, as originally filed.

pages NONE, filed with the demand.

pages NONE, filed with the letter of \_\_\_\_\_.

pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

☒ the claims, Nos. 1-15, as originally filed.

Nos. NONE, as amended under Article 19.

Nos. NONE, filed with the demand.

Nos. NONE, filed with the letter of \_\_\_\_\_.

Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

☒ the drawings, sheets/fig 1-8, as originally filed.

sheets/fig NONE, filed with the demand.

sheets/fig NONE, filed with the letter of \_\_\_\_\_.

sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

2. The amendments have resulted in the cancellation of:

☒ the description, pages NONE.

☒ the claims, Nos. NONE.

☒ the drawings, sheets/fig NONE.

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the ~~Supplemental Box~~ Additional observations below (Rule 70.2(c)).

4. Additional observations, if necessary:

NONE

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US98/13093

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)

Claims	<u>1-15</u>	YES
Claims	<u>NONE</u>	NO

Inventive Step (IS)

Claims	<u>1-15</u>	YES
Claims	<u>NONE</u>	NO

Industrial Applicability (IA)

Claims	<u>1-15</u>	YES
Claims	<u>NONE</u>	NO

**2. CITATIONS AND EXPLANATIONS**

Claims 1-15 meet the criteria set out in PCT Article 33(2)-(4), because the prior art does not teach or fairly suggest a masked expression cassette producing an antisense molecule that inhibits expression by the cassette in the absence of a target molecule.

----- NEW CITATIONS -----  
NONE

**PCT**WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau

## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup> :</b> <b>C07H 21/02, C12N 5/10, 15/87</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 98/58944</b> <b>(43) International Publication Date:</b> 30 December 1998 (30.12.98)
<b>(21) International Application Number:</b> PCT/US98/13093 <b>(22) International Filing Date:</b> 24 June 1998 (24.06.98)  <b>(30) Priority Data:</b> 60/050,772 25 June 1997 (25.06.97) US  <b>(71)(72) Applicant and Inventor:</b> BLACK, Charles, Allen, Jr. [US/US]; 1139 Judy Ann Place, Pittsburgh, PA 15237 (US).  <b>(74) Agents:</b> SPRUILL, W., Murray et al.; Alston & Bird, LLP, 1211 East Morehead, P.O. Box 34009, Charlotte, NC 28234-4009 (US).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> COMPOSITIONS AND METHODS FOR ACTIVATING GENES OF INTEREST		
<b>(57) Abstract</b>  Compositions and methods for activating genes of interest are provided. The compositions comprise a masked targeted expression cassette which expresses a gene product only in the presence of a target molecule. The cassettes are useful for the treatment of disease and for preventing the proliferation of neoplastic cells.		

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EE	Estonia	LR	Liberia	SG	Singapore		

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US98/13093**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :C07H 21/02; C12N 5/10, 15/87

US CL :435/69.1, 375; 536/24.5, 25.2

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 435/69.1, 91.3, 91.4, 172.3, 320.1, 375; 514/44; 536/23.1, 24.5, 25.2

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS, STN (Biosis, CAPLUS, LifeSci, Inpadoc, Medline, WPIDS).

Search terms: expression cassette, antisense, cap, translation initiation, toxin, Charles Allen Black.

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	HIRASHIMA et al. Engineering of the mRNA-Interfering complementary RNA Immune System Against Viral Infection. Proceedings of the National Academy of Sciences, USA. October 1986, Vol. 83, pages 7726-7730, see abstract.	1-15
A	COLEMAN et al. The Use of RNAs Complementary to Specific mRNAs to Regulate the Expression of Individual Bacterial Genes. Cell. June 1984, Vol. 37, pages 429-435, see abstract.	1-15

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

\* Special categories of cited documents:

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document published on or after the international filing date

\*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\*

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\*

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\*

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

\*&amp;\*

document member of the same patent family

Date of the actual completion of the international search

10 SEPTEMBER 1998

Date of mailing of the international search report

14 OCT 1998

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